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Food and Drug Administration

466 Fernandez Juncos Avenue
Puerta De Tierra
San Juan, Puerto Rico 00901-3223

WARNING LETTER
SJN-02-07

February 21, 2002

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Dr. Rafael Rizek
Blood Bank and Transfusion Services Director
Las Americas Laboratory and Blood Bank, Inc.
400 Domenech Avenue, Suite 203
Hato Rey, PR 00918

Dear Dr. Rizek:

From December 4 to December 12, 2001 an investigator from our office conducted an inspection of your licensed hospital blood bank, located at the above listed address. The investigator documented deviations from the requirements of Biological Products: General, Title 21, Code of Federal Regulations, Part 600 (21 CFR 600) Current Good Manufacturing Practices (GMP's) for Blood and Components, 21 CFR 606 and Additional Standards for human Blood and Blood Products, 21 CFR 640. These deviations cause the Blood and Blood products manufactured and tested by your firm to be adulterated within the meaning of section 501 (a) (2) (b) of the Food, Drug and Cosmetic Act (the Act).

The deviations reported were as follows:

1. Failure to store and handle platelets as described in 21 CFR 640.24(d) and 21 CFR 640.25(a), which require that, immediately after separation, the platelets be stored at either 20 to 24°C with gentle agitation or 1 to 6°C with optional agitation.

   The inspection found that platelets are routinely stored in a shaker at room temperature with no air conditioning or temperature monitoring.

2. Failure to promptly notify the Center for Biologics Evaluation and Research (CBER) of errors as required by 21 CFR 600.14.

   The inspection found that an error, which resulted in the issuance of a unit of incorrect group and type for transfusion in June 2000, was never reported to CBER.

3. Failure to have a system to record, document and investigate discrepancies related to the quality of blood products as required by 21 CFR 606.100 (c).

4. Failure to follow appropriate donor screening procedures as required by 21 CFR 640.3. For example during the inspection the following was observed:

   a. The donors were interviewed in the reception area, which did not provide adequate privacy, and the interviews were interrupted for the conduct of other business by the interviewer.

   b. The interviewer did not physically examine the donors' arms for indication of intravenous drug use.

   c. The interviewer did not check the donor deferral files to determine if prospective donors were previously deferred due to positive viral marker test results.

   d. Self-exclusion cards, which are required by your procedures to be completed before donations are released for transfusion, were not provided to donors during the inspection. In addition, review of the records found several additional units, which were released without the self-exclusion card being included in the records.

5. Failure to maintain adequate records of the processing and distribution of blood as required by 21 CFR 606.160(b) & (c). For example:

   a. At least 45 records for the period from 1/1/00 to 12/12/01 did not include a record of the individual who physically received the unit from the blood bank.

   b. The blood types of at least two units were illegible in the cross-match records.

   c. There was no Du test record in the log for at least one unit, which was reported as Rh negative.

The above identified deviations are not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment with all requirements of the federal regulations.

You should take prompt measures to correct these deviations. Failure to promptly correct these deviations may result in regulatory action without further notice. Such action includes seizure and/or injunction.

Please notify this office in writing, within 15 working days of receipt of this letter, of the specific steps you have taken to correct the noted violations and to prevent their recurrence. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your reply should be sent to the address on the letterhead above to the attention of Mary L. Mason, Compliance Officer.

Sincerely,

Wayne Mathews for

Mildred R. Barber
District Director